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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Christine Noel

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11/30/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.

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ALEXANDRIA, VA 22314

EXAMINER

YU, GINA C

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

11/30/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/685,505	Applicant(s) NOEL ET AL.	
	Examiner GINA C. YU	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 8-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 8-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of amendment filed on July 10, 2009. Claims 1, 6, 8-24 are pending. Claims 21-24 remain withdrawn from consideration.

The claim rejections made under 35 U.S.C. § 112 first and second paragraphs as indicated in the previous Office action dated February 13, 2009 are withdrawn in view of the claim amendment made by applicant.

The claim rejections made under 35 U.S.C. § 103 (a) as indicated in the same Office action are withdrawn in view of the claim amendment in part and applicant's remarks in part.

New rejections are made as discussed below.

Claim Rejections - 35 USC § 103 (New Rejections)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6, 8-18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 02/03952) in further view FR 2771632 to Stoltz or US 20010002257 (English equivalent).

Robinson teaches skin care composition comprising silicone elastomer and a skin care active with reduced residue and tackiness/stickiness. See abstract; p. 5, lines 5 - 10. The composition may be in an oil-in-water emulsion. See page 32, lines 15-20 and examples. The composition comprises silicone elastomer in an amount of 1-20%. The organopolysiloxane is preferably an addition reaction curing organopolysiloxane in the presence of a platinum catalyst. The instant organopolysiloxane is taught. See

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pages 10-14. The carrier for the elastomer serves to suspend and swell the elastomer particles to provide elastic, gel-like matrix. The carrier is used in an amount of 5-50% and may be volatile or non-volatile oil. See page 14. The composition further comprises thickening agents including carboxylic acid polymers, polyacrylate polymers, polysaccharides, gums, and instant polyacrylamide polymer (Sepigel) in the amount of 0.1-5%. See page 19-22 and particularly page 20, line 30 to page 21, line 7. The reference teaches the use of active agents including anti-acne agents and anti-wrinkles agents such as N-acetyl-derivatives, for instance N-acetyl-cysteine and antioxidants such as methionine, proline, or lysine in an amount of 0.1-10% to provide UV protection. See p. 46, lines 13-29. The composition may be formulated into facial skin cosmetics, eye cosmetics, anti-wrinkle creams, lip cosmetics, foundations, etc. The composition is useful in reducing the appearance of wrinkles, scars, skin roughness, blemishes, pores, etc.

Robinson does not teach the instant lipoamino acid.

Stoltz teaches the use of N-acyl amino acids for formulating cosmetic compositions that provides soothing/protecting properties, retards skin aging, and provides disinfecting properties to treat acne. The amino acids taught are undecylenoyl glycine and octanoyl glycine. See abstract. Stoltz further teaches an active principle comprising capryloylglycine (octanoylglycine) at concentration of 1.6 % by weight of the total composition and extract of cinnamon effectively produces an anti-lipase activity. See also EXAMPLE B). EXAMPLES B), C) and E) also indicates the efficacy of a combination of the capryloylglycine and the plant extract in inhibition of elastase,

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inducing anti-5-alpha reductase activity, and inhibition of antimicrobial activity.

Composition A , which contains 25 % by weight of capryloylglycine and an amount of cinnamon extract is added to example formulations at various concentration levels, including 1 %, 0.5 %, and in a range of 0.5-1 % by total weight of a composition. The formulations are used to treat greasy and acne-prone skin.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the teachings of Robinson by incorporating active ingredient of Stoltz which includes capryloylglycine. One would have been motivated to do so since Stoltz teaches that octanoyl glycine is used with a plant extract as a cosmetic agent in an effective amount to provide soothing/protecting properties, retards skin aging, provides disinfecting properties to treat acne and greasy skin, and Robinson teaches adding anti-wrinkle and/or anti-acne agents in the silicone-elastomer emulsion to make a cosmetic composition with a good sensory feel. Since Stoltz teaches the lip amino acid is used in various lotion and cream formulations, by combining the teachings of the prior arts, a skilled artisan would have had a reasonable expectation of successfully producing a stable skin care composition comprising the active principle of Stoltz which would effectively control greasy and acne-prone skin, without residue and stickiness.

Claims 1, 6, 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorant et al. (EP 1055406 or US 6,465,402, the English equivalent) in view of Fotinos (US 6,346,255).

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Lorant teaches an oil-in-water emulsion comprising an organopolysiloxane elastomer in the oily phase and a water-soluble polymer in the aqueous phase. The oil-in-water emulsions are stable and thus do not contain a conventionally used surfactant. Lorant teaches emulsifiers are potentially irritating the skin, eyes and scalp and thus it is advantageous to formulate an emulsion without using emulsifiers to stabilize the emulsion. The compositions provide fresh and comfortable feel during application to the skin, unlike conventional compositions. See abstract and column 1, lines 18-36.

Lorant teaches the use of α , ω dimethylvinylpolydimethylsiloxane. See column 4, line 50 and the elastomer gel is utilized in an amount of 0.03-40% and preferably 1.5-20%. See column 5, lines 59-66. The water-soluble polymers that are suitable include carboxyvinyl polymers; acrylic or methacrylic copolymers; natural gums; polysaccharides; acrylamide polymers and copolymers; vinyl ether copolymers; or cationic polymers, such as polyquaternium. Preferable acrylamide copolymers include the crosslinked copolymer of acrylamide and of 2-acrylamido-2-methylpropanesulphonic acid, in particular the mixture sold under the name Sepigel 305. The polymer is used in an amount from 0.1 to 10%, preferably 0.2 to 5%, and more preferably from 0.5 to 2%. See column 6, line 5 to column 9, line 40. The oils in the oil phase include non-volatile and volatile oils and the oily phase can range from 1 to 50%. See column 9, line 40 to column 10, line 25. The composition comprises active agent in the amount of 0.01-30% and may be antioxidants, lipophilic active agents, etc. Preferably the active agents include moisturizing agents; keratolytic agents; salicylic acid and its derivatives; vitamins; depigmenting agents; slimming agents; screening agents; and any active

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principle appropriate for the final purpose of the composition. See column 10, lines 32-60. The composition is suitable for treating dry skin and/or dry lips. See column 11, lines 1-7.

Lorant does not teach the use of the instant lipophilic amino acids.

Fotinos teaches a method of improving skin appearance with a skin permeation enhancer and an active agent. See abstract. Fotinos teaches the use of various lipoamino acids such as acylation products, which are anti-elastase and anti-collagenase agents (anti-wrinkle agents); the use of lipoamino acids such as lysine and lauroylmethionine as antioxidants; lipoamino acids such as instant capryloyl glycine as seboregulators; lipoamino acids such as lysine PCA and related compound as hydratives. See column 7, lines 36-65. Examples 37-40 teaches cosmetic pads containing seboregulators, wherein the active ingredient is used at 1 % w/w on a dry basis and at 16.13 % by weight of coating compositions. See examples 38 and 40. The reference also indicates that cosmetic actives are typically present in cosmetic pads in an amount of 1-20 % by weight. See col. 8, lines 38 - 55. Furthermore, the reference teaches that it is a conventional practice in cosmetic art to formulate cosmetic agents in various forms, either in lotion or patches. See col. 4, lines 60-66. Thus discovering the workable effective amount for the seboregulators in a liquid vehicle would have been well within the skill of the art.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teaching of Lorant and Fotinos and utilize lipoamino

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acids as the active agent in Lorant's composition. One would have been motivated to do so since Fontinos teaches lipoamino acids have a large number of applications in the cosmetic field including anti-wrinkle agents, antioxidants, hydrating agents, and seoregulators and Lorant teaches the use of any skin active agent including antioxidants and moisturizing agents, depending on the final purpose of the composition. Therefore, the selection of the active agent is prima facie obvious depending on the desired aesthetic benefit provided by the skin care composition. Furthermore, a skilled artisan would have been motivated to use capryloyl glycine in particular if one desired to provide a composition that controls sebum, which causes acne.

With respect to claim 6, finding a workable weight amount of capryloyl glycine in the Lorant emulsion would have been well within the skill of the art. The court in In re Aller has state, "were the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, the Fontinos teaches the general range of cosmetic active ingredient for cosmetic patch or pad, and teaches that seoregulators are used in 16.13 % by weight of a coating composition or 1 % by dry weight. Also suggested in the reference is the conventional practice in cosmetic art that same cosmetic actives are incorporated into different formulations, such as lotion. Since Fontinos teaches capryloyl glycine is used in cosmetics to control sebum, the parameter for the optimization of the weight amount is clearly taught. Thus discovering the optimum weight amount of the capryloyl glycine as

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a sebum regulator in the Lorant silicone emulsion would only take routine experimentations in the art.

Response to Arguments

Applicant's arguments filed July 10, 2009 have been fully considered but they are unpersuasive.

At issue in this case is whether, applicant's discovery of emulsion stabilizing effect of capryloylglycine should form the basis for patentability for an emulsion comprising the amino acid, when the prior arts, at the time of the present invention, taught different utilities of the same amino acid, and suggested such use in cosmetic compositions which includes emulsions. Examiner asserts that applicant's discovery of a property not described in the prior art does not make the compositions that would have been made as motivated and suggested by the prior arts new or nonobvious.

Applicant continues to assert the Rule 132 declarations filed on November 1, 2006 and July 24, 2007 provide evidence for unexpected results of using capryloyl glycine and/or undecylenoylglycine as an emulsion stabilizer. In response, pursuant to the well-settled patent law in Ex parte Obiaya, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, applicant appears to assume that a skilled artisan would have expected similar properties from lipoamino acids. On the contrary, Lorant and Fontinos have already singled out capryloylglycine from other amino acids for its specific utility as a sebum regular and/or

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anti-acne agent. When the prior arts already have disclosed capryloylglycine used in cosmetic compositions for these cosmetic benefits, applicant's discovery of its emulsion stabilizing property cannot be the basis for patentability over the compositions that would have been made as motivated and suggested by the prior arts. Examiner maintains the position that prima facie case of obviousness has been properly made in each of the Robinson/Stoltz and Lorant/Fontinos rejections as both sets of references provide motivations to use applicant's lipoamino acids for reasons that are independent from emulsion stabilization. Both references teach and suggest the effective amount in which the amino acid is used to achieve the cosmetic functions recognized in the prior arts, i.e., sebum control and/or antimicrobial effects, etc., and such range is well within the presently claimed range of the same active ingredient.

Applicant also states that the emulsion stability effect is unexpected and surprising when the emulsion contains a significant amount of elastomer and hydrophilic polymers. However, Claim 1 requires as low as 1 % of the silicone elastomer and no hydrophilic polymers may be present in the composition of the claim. Thus applicant's description of the present invention is not commensurate with the scope of the claims.

With respect to the Lorant/Fontinos rejection, applicant also asserts that the fact that Fontinos' inventions, patches and pads, are structurally different from Lorant's emulsion would have negated any motivation to use capryloylglycine with expectation to stabilize the Lorant composition. As discussed above in the rejection, incorporating a cosmetically active ingredient in different formulation is well within the skill of the art,

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and Fontinos provides another reason to utilize capryloylglycine in a cosmetic composition other than for the advantage that applicant has found in this case.

Applicant also asserts that the holding of Ex Parte Whalen applies to the present case. In Whalen, the examiner's stated motivation to modify the prior art teachings to adjust the viscosity of the claimed composition was not supported neither by facts or scientific rationale. However, the facts of the present case are different from those of Whalen because, unlike in that case, both Stoltz and Fontinos provide numerical values of the effective amount of the active ingredient and teaches the parameter for a skilled artisan to optimize, i.e., to achieve effective sebum regulation and/or acne inhibition as an active ingredient in a cosmetic composition. The effective amount to obtain such cosmetic benefits disclosed by the prior arts is also within the applicant's weight range. The Whalen case does not necessarily stand for the position that a prima facie case of obviousness requires same motivation to modify prior arts in the rejection as applicant's reason to do so.

Thus, examiner views that Ex parte Obiaya would be the proper precedent to apply in the present case, and the facts of the present case would still favor maintaining the obviousness rejections above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605.

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The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GINA C. YU/
Primary Examiner, Art Unit 1611